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# PEROXOCHLORIC ACID, DERIVATIVES AND ANIONS, SALTS THEREOF, METHOD FOR PRODUCING THEM AND USE OF THE SAME [PEROXOCHLORSÄURE, DERIVATE UND ANIONEN, SALZE DAVON, UND VERFAHREN ZU DEREN HERSTELLUNG UND VERWENDUNG]

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Summary of Invention

This invention relates to chlorohydroperoxide, peroxochloric acid, their derivatives, anions, derivatives thereof, or salts thereof. It also relates to the production of these compounds and their use in the pharmaceutical and especially the medical fields as medications and disinfectants, such as in cosmetics and in medical care, as tissue-compatible deodorants as well as in the fields of essential foods processing and technology, in particular, in the conservation of essential and nonessential foods, and as bleaching agent as well as for drinking water disinfection, degermination of plants and fruits in agriculture and as oxidant in industrial chemistry as well as for waste-gas purification.

Background of Invention

Oxidants are used in many different ways in industrial chemistry, in hygiene and in food conservation, in cosmetics and also in pharmacy.

According to Polly Matzinger (Polly Matzinger: "Tolerance, Danger, and the Extended Family" in Annu. Rev. Immunol., 1994, 12), cells that are lytic, nonapoptotic dying cells by force, that is to say, by massive radiation action, toxic substances, parasitary, bacterial or viral viruses, transmit danger signals, which must last so that the body's

inherent defensive strength can become clinically effective in an optimum fashion; that defensive strength requires a nonspecific co-stimulation by means of antigen-presenting cells (for example, macrophages) in addition to the actual antigen signal.

In case of a forcible, nonapoptotic destruction, phagocytes (so-called microphages and macrophages) are responsible or the removal of cell debris. Oxidatively effective oxygen metabolites are released during this cell debris removal. Hydrogen peroxide ($H_2O_2$) is the best-known representative. In-vitro experiments showed that $H_2O_2$, in the micromolar area, can lead to an immune modulation of lymphocytes by way of activation of the transcription factor NF-χB (R. Schreck et al., The EMBO Journal 10 (8), 2247-58 (1991); M. Los et al., Eur. J. Immunol.

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25, 159-65 (1995)). The team of Avraham Novogrodsky was the first who showed in vitro that certain oxidants (Bowers, W. E.: "Stimulation of Lymphocytes with Periodate or Neuraminidase plus Galactose Oxidase - NAGO," pp. 105-109, Review in Immunochemical Techniques, Part K, Methods in Enzymology, Vol. 150, 1987), among other things, also $H_2O_2$, which is formed in the body itself, increase the lymphocyte proliferation caused in a (co)mitogenic fashion by means of antigen stimulation if macrophages are simultaneously in the lymphocyte culture

(Stenzel, K. H., Rubin, A. L., Novogrodsky, A.: "Mitogenic and Comitogenic Properties of Hemin.," J. Immunol. 127, 6; 2469-2473 et ibid. cit. ref.). If the oxidatively active oxygen metabolites in the body are not formed to a sufficient extent, then any immune defense is incomplete or it will be entirely missing so that a tolerance or pathological energy will be developed. Chronic infections and tissue cicratization will result when they are produced excessively or in a smoldering, excessively long-lasting manner.

According to these findings by Avraham Novogrodsky in conjunction with the hypothesis of Polly Matzinger, one must assume that oxidatively active oxygen compounds have a therapeutic effective, particularly in such clinical situations where their endogenous formation remains deficient or abates before the damage to the body was completely restored and before the viruses have been completely eliminated. One must expect that treatment will be successful, especially in cases where the viruses, of course, do infect the cells but do not destroy them so that there are no danger signals. By way of example, we might mention here infections with leprosy and tubercle bacilli and those with herpes and AIDS (HIV) viruses.

The successful clinical use of potassium bichromate for healing putrescent chronic wounds was reported already in 1906

(Fenwick, J.: "The Treatment of Cancer by the Use of Potassium Bichromate," British Medical Journal, March 6th, 1909, 589-591).

Numerous other publications, which have come out in the meantime, show that hydrogen peroxide, formed in a physiological manner in the body as well as the in vivo, even more unproductive peroxonitrite that can develop out of the likewise physiological nitroxide and hydrogen peroxide, can likewise produce wound-healing effects in which a positive immune modulation is involved in an essential fashion. For example,

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EP-A-0 390 829 describes a method for increasing the syngenic intradermal cell proliferation by means of growth factors in man with hydrogen peroxide injections. Such a comitogenic increase in the effectiveness of the growth factor of Interleukin-2 was described in 1987 also for periodate (Wang, J. et al., The American Journal of Medicine, 1987, 83; 1016-1023).

It was found that (co)mitogenic oxidants have intolerable side effects such as, for example, in the case of bichromate, the carcinogenic effect of chromoxide, which has become known in the meantime. In the case of periodate: excessive sensitization to iodine and toxic effect. This is why clinical employment must rather laboriously be managed as "adoptive transfer," that is to say, the blood cells are taken out, they are treated in vitro, and they are then put back in vivo, as was described in

the above-cited work by J. Wang et al., 1987. In the case of NAGO: foreign protein sensitization. In the case of $H_2O_2$: formation of toxic oxygen radicals. Here again, their use as medication is blocked by technical problems, for example, in the case of $H_2O_2$, there is its poor durability in a diluted aqueous solution; sensitization to catalysis with massive oxygen gas release. In the case of oxidative ubiquinone derivatives, there are galenic problems and the bioavailability is limited.

It was therefore impossible until now to transfer the experimentally documented immune pharmacological effect of (co)mitogenic oxidants to tissue regeneration/wound healing to defense against infection or to increasing the immune response to clinical practice in which, along with local use, is also desirable to pursue a systematic application method, mostly in the form of intravenous administration.

The patent literature describes some chloroxygen preparations, which are used especially in those technical areas where they are employed as oxidants not only in industrial technology as bleaching agents and deodorants but where they were also recommended for paramedical use as in cosmetics for skin and hair care, for household care, in the field of sanitation for hygiene and/or as disinfectant of surfaces (US 2,701,781; US 3,123,521) and/or wounds (US 4,084,747; EP-A-0 744 895), as conservation agents for cheeses (US 3,147,124), for

drinking and bathing water preparation (US 4,296,103; DE-A-44 05 800, DE-A-19 518 464; WO 96/33947; WO 97/06098). US-A-4,296,103, EP-A-0 136 309, US-A-4,507,285 and EP-A-0 255 145

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describe the use of chloroxygen preparations as medications. However, the described chloroxygen preparations do not meet the requirement criteria of modern medication licensing, which criteria state that the pharmacodynamics of the preparations of a chemically defined compound must be capable of being associated as a so-called active substance with respect to which the particular medication product is to be standardized, last but not least in order thus to guarantee a steadfast medicine quality.

The object of the invention therefore is to provide an oxidant that does not feature the abovementioned disadvantages. In addition to the usual usability for oxidation purposes in the technical and medical fields as well as for disinfection, this oxidant should also offer the possibility of formulation as medication for local as well as systemic use, for example, for intravenous administration, for example, as medication for tissue regeneration, would healing and for defense against infection or for increasing the immune response. Moreover, it is to meet the requirements of modern medication licensing.

Data on Drawings

Fig. 1 shows the correlation between the pKa value of acids (ROH; x-axis) and pertinent peroxide acids (ROOH; y-axis). (1) = $HOONO_2/HONO_2$ pair; (2) = $ClCH_2C(O)OOH/ClCH_2C(O)OH$ pair; (3) $HC(O)OOH/HC(O)OH$ pair; (4) = HOONO/HONO pair; (5) = $CH_3C(O)OOH/CH_3C(O)OH$ pair; and (6) $H_2O_2/H_2O$ pair, (7) shows the value for $O_2ClOOH$ (invention-based acid)/$O_2ClOH$ pair.

Detailed Description of Invention

It was found quite by surprise that this problem can be solved by providing a definable chlorohydroperoxide as well as of the latter salts and anions. The chlorohydroperoxide, thus provided according to the invention, has the formula $HOOClO_2$, where chlorine is pentavalent, and it behaves like an acid that, in an aqueous environment supplies the anion $-OOClO_2$. It is therefore described as peroxochloric acid and its anion is called peroxochlorate.

The combination of two peroxochlorate ions can, along with

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separation of an oxygen molecule, lead to derivatives of peroxochlorate with a peroxogrouping and two chlorine atoms with differing valence. These ions have the sum formula $Cl_2O_6^{2-}$.

Chlorohydroperoxides represent a compound class, which so far has never been made or isolated neither as such nor in its anionic form, in substance, or in solution. Among the chlorohydroperoxides, only theoretical stabilities of molecules

have been calculated or predicted for the gas phase in the technical literature. The calculations partly produced contradictory results. In the gas phase of the atmosphere, it has likewise not been possible to find any reference to the existence of long-lived hydroperoxides of chlorine (Finkbeiner, M., Crowley, J. N., Horie, O., Müller, R., Moortgat, G. K., and Crutzen, P. J., J. Phys. Chem. 99, 16264-16275 (1995)).

It is reported in the literature that mixing chlorodioxide with hydrogen peroxide results in chlorite and oxygen (Bogdanchikov, G. A., Kozlov, Yu. N. and Berdnikov, V. M.: "The Mechanism of the Elementary Act of $HO_2$ Anion Oxidation by $ClO_2$ Radical in Aqueous Solution," Khim. Fiz. 1983 (5), 628-636). Ni, Yonghao and Wang, Xiaolan ("Mechanism and Kinetics of Chlorine Dioxide Reaction with Hydrogen Peroxide Under Acidic Conditions," Canadian J. of Chemical Engineering 75, 31-36 (1996)) work with a pH value of 3.63 to 6.10 and get chlorite according to the following reaction equation:

$$2ClO_2 + H_2O_2 + 2OH \Rightarrow 2ClO_2 + O_2 + 2H_2O$$

As intermediate product, they postulate a compound with a quadrivalent chlorine.

It was found quite surprisingly as part of the invention at hand that it is possible to make and to isolate stable peroxochloric acid and stable salts or anions thereof. It turned out, for example, that stable peroxochloric acid or its

anions and salts are obtained by mixing chlorodioxide with hydrogen peroxide if one works with pH values of the same value or above the pKs values of peroxochloric acid ($HOOClO_2$).

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Preferably, one works with a pH value of 6.5 and more, particularly preferably in the pH range of 10-12.

One object of the invention therefore involves peroxochloric acid or its salts; as well as peroxochloric acid and its slats or anions in an aqueous solution. The invention furthermore comprises additional oligomeric derivatives of peroxochlorate with mixed-valent chlorine atoms and their salts or anions in an aqueous solution as well as the carbon dioxide adduct as acid, as anion in solution, or as salts thereof. The oligomeric derivatives and/or the carboxylic acid adducts are hereafter referred to as "derivatives," in particular, $Cl_2O_6^{2-}$ anions or salts thereof, or $O_2Cl$-O-O-C(=O)O anions or salts thereof.

Peroxochloric acid has a pKa value (synonymous pKs value) of 6.5 ± 0.2 and thus differs from the known chloroxygen acids, as can be seen in the table below, where we also find additional characteristic parameters of the acid or of the latter's anion in comparison to those of the known acids.

Along with the pKa value, the peroxochlorate ions can be characterized also by means of a characteristic Raman band at 1051 $cm^{-1}$ (Table 1).

Table 1:

| Säure/Base-Paar | PKs-Wert der Säure | Bandenlage [$cm^{-1}$] im Raman-Spektrum des Säureanions | UV-Spektrum des Säureanions |
|---|---|---|---|
| $HOCl/ {}^{-}OCl$ | 7,6 | 729 ± 1 (stark) | $\lambda_{max}$ = 298 nm |
| $HOClO/ {}^{-}OClO$ | 2,0 | 799 ± 1 (stark) | $\lambda_{max}$ = 260 nm |
| $HOClO_2/ {}^{-}OClO_2$ | 0,0 | 933 ± 1 (stark) | Flanke $\lambda$<215 nm |
| $HOClO_3/ {}^{-}OClO_3$ | -10 | 937 ± 1 (stark) | Flanke $\lambda$<205 nm |

[Key (left to right): 1) Acid/base pair; 2) PKs value of acid; 3) Band position [$cm^{-1}$] in Raman spectrum of acid anions; 4) UV spectrum of acid anion; 5) Strong].

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|---|---|---|---|
| $HOOClO_2/ {}^{+}OOClO_2$ | 6,5 ± 0,2 | 1051 ± 1 (stark), 933 ± 1 (schwach) | Flanke $\lambda$<230 nm |
| Carbonat, $CO_3^{2-}$ | | 1069 ± (stark) | |

[Key: 1) Strong; 2) Weak].

In particular, the compound can also be distinguished from other oxo-compounds and of carbonate (Table 2).

Table 2:

| Verbindung | RAMAN-Linie ($cm^{-1}$) |
|---|---|
| Wasserstoffperoxid | 878 ± 1 (stark) |
| Peroxonitrit, $ON\text{-}OO^-$ | 1050 ± 1 (stark) |
| Peroxosalpetersäure, $O_2N\text{-}OOH$ | 945 (O-O-Streckschwingung) |
| Peroxochlorat, $O_2Cl\text{-}OO^-$ | 1051 ± 1 (stark), 983 ± 1 (schwach) |
| Oxone®, $^-O_3S\text{-}OOH$ | 1062 ± 1 (stark), 983 ± (schwach) |

[Key (top to bottom, left to right): 1) Compound; 2) Hydrogen peroxide; 3) Peroxonitric acid; 4) Raman line; 5) Strong; 6) Yield fluctuation; 7) Weak].

It is especially the similarity with the peroxonitrite band at 1050 $cm^{-1}$ that points to the structural relationship.

The stability of peroxochloric acid in an aqueous solution can be given by the half-life for its decay at room temperature. It is $t_{1/2}$ = 6 minutes. In the gas phase, it was possible to show in the meantime that the chloroperoxo bond in terms of its character is somewhat between a van-der-Waals bond and a covalent bond.

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Fig. 1 shows that the theoretical value ("prognosis value") for $O_2ClOOH$ should be

$$PKa\ (ROOH) = 6.11 \pm 0.14 * 0.33 \times 0.021 \times pKa\ (ROH)$$

The pKa value (7) found amounting to 6.5 ± 0.2 is on the straight line and thus confirms the structure of the invention-based compound.

The peroxochlorate ion, in itself, turns out to be a stable compound. But since in an aqueous solution it is in balance with the peroxochloric acid, it decays as a function of the pH value. The half-life (in terms of days) for the decay of the peroxochlorate ion can be calculated as a function of the proton concentration with the following equation:

$t_{1/2} = 0.00412 + 3.85 \times 10^{-9}/[H^+]$ days (Equation 1)

At pH 11, it is about 400 days; at pH 12, it is about 10 years.

To improve the durability of the peroxochlorates in an aqueous environment, it is therefore preferable to keep the peroxide values higher for storage, for example, at a pH value of 10, 11, 12 or more, in particular, at a pH of 10-13.

From peroxochlorate via the reaction:

2 "$OOClO_2 \rightarrow Cl_2O_6^{2-} + O_2$,

One can form the desoxo dimer, where the chlorine atoms are present in different oxidation steps (+3 and +5). These dimers are likewise new and the pertinent acid and especially its salts and anions as well as their production and use are also objects of the invention.

Peroxochlorate can be converted into the carbon dioxide adduct via the reaction with carbon dioxide or their carbonate anions or hydrogen carbonate:

$$O_2ClOO^- + CO_2 \rightarrow O_2Cl\text{-}O\text{-}O\text{-}C(=O)O^- \text{ and/or}$$

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$$O_2ClOO^- + HCO_3^- \rightarrow O_2Cl\text{-}O\text{-}O\text{-}C(=O)O^- + OH^-$$

These peroxoderivatives with carboxylic acid are also new and they, especially their salts and/or anions as well as their production and use, are also objects of the invention (see the derivatives of peroxonitrite, $ONOO^-$, which, under similar conditions, forms $ONOOC(=O)O^-$ (Radi et al., Methods Enzymol., Vol. 301, 353-67 (1999)).

Whenever "anions" are mentioned in this disclosure, that includes the presence of the required counterions (above all, in solution). The term "anions" is above all intended to express the idea that, in solution, the peroxochlorate anion is the more stable form when compared to the protonized acid.

Peroxochlorate and the dimer as well as the carboxylic acid adduct can be present as a mixture according to the invention.

The invention also relates to the method for the production of peroxochloric acid or its derivatives, anions and/or salts thereof. This process consists of mixing chlorodioxide with aqueous or water-containing hydrogen peroxide at a pH value of

6.5 or more, particularly a pH of 10-12. It is preferable to keep the pH value constant.

The mixing can be done in an aqueous environment or in a water-containing environment. For example, along with water, we can also have solvents that can be mixed with water, such as, for example, alcohols, such as, for instance, alkanols, such as methanol, ethanol or the like, or mixtures thereof.

Optionally, one can also start with other chloroxides. For example, chloromonoxide, preferably in its dimeric form ($Cl_2O_2$), can also be mixed with a hydroperoxide (preferably oxygen peroxide) to get the desired product. The mixing is done in the same pH range as given for chlorodioxide.

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The reaction temperature can be increased, for example, up to about 50°C; in case of purely aqueous systems, the lowest temperature preferably is about 0°C. When additional organic solvents and/or high concentrations of the involved reagents are present, then one can also use lower temperatures, that is to say, temperatures below the freezing point of water. One preferably works at room temperature.

The chlorodioxide needed for mixing is available to the expert and can be made in the usual fashion. For example, it can be made by reaction of a chlorite with an acid (for example,

sodium chlorite with sulfuric acid) or by reduction of chlorate, for example, with sulfurous acids.

The chlorodioxide, thus obtained, can be released in the known manner, possibly after removal of present traces of chlorine (Granstrom, Marvin L.; and Lee, G., Fred., J. Amer. Water Works Assoc. 50, 1453-1466 (1958)).

If the chlorite that is used for the production of $ClO_2$ is contaminated with carbonate, then one gets $ClO_2$ that is contaminated with $CO_2$ and/or one gets the above-described carboxylic acid adducts. To absorb the carbon dioxide, the gas flow containing chlorodioxide and carbon dioxide should be conducted through a water bottle filled with caustic solution. But it is better to release the impurities consisting of carbonate by means of fractionated crystallization of the sodium chlorite that has been used. Contamination of the peroxochlorate with carbonate can be easily recognized in the Raman spectrum. In place of the sharp band at 1051 $cm^{-1}$, we get a double band at 1069 $cm^{-1}$ (wide) and the band of 1051 $cm^{-1}$ (sharp), which is important in the context of the invention.

The chlorodioxide can be conveyed with an inert gas such as nitrogen or a rare gas such as argon, but also by air or oxygen so as to react with the hydrogen peroxide. For example, it is possible to make the chlorodioxide in a first reaction vessel and to pipe it, together with the mentioned gases or a mixture

thereof, into a second reaction vessel in which the hydrogen peroxide is present in a water-containing or aqueous solution.

The pH value of the reaction mixture is kept equal to or

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greater than 6.5 by adding a base. It is preferably to keep the pH value constant. That can be done either manually or automatically by a pH stat unit.

As bases, one can use the customary inorganic or organic bases such as alkaline lyes, for example, caustic soda or caustic potash solution or alkaline earth hydroxides, ammonia or organic bases, such as nitrogen bases. One can also use the hydroxides of quaternary ammonium salts, in particular, alkyl, such as trialkylammonium hydroxides or zinc hydroxides.

The content of hydroperoxide in the reaction mixture, for example, can be determined by potentiometric titration with an acid, such as, for example, hydrochloric acid.

The solution obtained according to the above-described example can be employed as such or also in a modified form. For example, any excess hydrogen peroxide can be removed in the usual manner, for example, with a heavy metal compound such as manganese dioxide.

It is also practical to perform the reaction in the presence of additional chlorites, for example, alkali metal

chlorite, for example, sodium chlorite. By means of this addition, the balance of the decay reaction

$$O_2ClOO^- \Leftrightarrow ClO_2^- + O_2$$

is shifted to the left, that is to say, the peroxochlorate is stabilized.

To improve the durability of the reaction product, it is, for example, advisable to store at a higher pH value, for example, a pH value of 10 or more. This pH value can be set with a suitable base as described above in connection with the production method.

To get a chlorite-free peroxochloric acid, its salts or solutions thereof, it was quite surprisingly possible to expel

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or catch the free acid by lowering the pH value below 6, for example, to a pH value of 5 or less, out of the mixture containing the chlorate ion [sic] with an inert gas such as a rare gas, for example, argon or nitrogen. It can, for example, be caught in a base such as an alkali metal base, an alkaline earth metal or zinc base or a nitrogen base, such as ammonia or an organic amine. But it is also possible to freeze the free gaseous-obtained acid in a cooling trap (for example, at -100 to -190°C).

For example, it is possible to intercept the acid expelled with argon to the extent of 70% with 2M of caustic soda out of a

2.7% by weight solution of the acid in the approximately 50-fold quantity of sodium chlorite. A UV spectrum of the solution shows by the absence of the peak at 260 nm that no sodium chlorite is present in the solution.

Another object of the invention therefore consists in a method for the production and isolation of peroxochloric acid and its derivatives as well as salts thereof, where chlorodioxide is mixed with an aqueous or water-containing solution of hydrogen peroxide at a pH value of ≥ 6.5, preferably 10-12, whereupon the pH value is pushed below 6 and the free acid or its derivative is expelled out of the solution and caught as gas by means of an inert gas. To get products that are free of carbon dioxide, one preferably works here with a hermetic air seal, for example, using nitrogen, oxygen or argon.

If the acid is intercepted in an aqueous solution of a base, then one gets the chlorite-free corresponding salts in solution. The solutions can be reduced in the usual manner, for example, by evaporation under reduced pressure, whereby one can isolate the salts in a crystalline form or by treatment with a gas flow such as argon or nitrogen. The structure can be confirmed by an x-ray structure analysis. As counterions, one can consider all metal cations and organic cations, such as those of nitrogen bases, in particular, quaternary ammonium salts. The particular practical purpose will indicate which

cations are particularly suitable. For pharmaceutical uses, one especially prefers alkaline earth or alkaline metals, preferably $Na^+$ or $K^+$ or $Zn^{2+}$, while for technical applications, one can also employ organic cations, such as cations of nitrogen bases, in particular, alkyl ammonium cations, such as trialkylammonium cations or, above all, quaternary ammonium cations.

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A hint as to the presence of the salts is supplied also by the fact that peroxochlorate anions can also be found again after the redissolution of a dried salt by means of titration: For example, a solution with a pH of 10.5, which has 0.1 mole of sodium peroxochlorate (content determined by titration), is evaporated to dryness and is then again absorbed in water. The titration of an aliquot part with 0.1 M hydrochloric acid preferably leads to a rediscovery of 80% to 100%, especially 90% to 99.95%, for example, 95%.

It is practical and preferred to store the acid as well as the salts by excluding light and, from that, to make aqueous solutions with high pH values, for example, the pH values of 10, 11 or 12 and even more, especially in the range of 10 to pH 13, in order to achieve long storage times. From such solutions, depending on the need, the free acid can again be obtained, as described above, and can possibly be converted into solutions with a desired pH value or into salts.

The invention-based peroxochloric acid or its derivatives or the anions or especially the salts thereof are preferably present in an essentially pure form, that is to say, in a solution related to the total molarity of the dissolved peroxides, in particular, to the extent of more than 80%, preferably more than 90% of purity, preferably more than 95% by mole of purity; in the case of the solid salts in more than 80% by weight of purity, preferably with more than 90% by weight of purity, in particular, more than 95% by weight of purity.

The invention-based peroxochloric acid, its derivatives or anions and salts thereof can be used as such and especially in an aqueous or water-containing solution as oxidants for the most varied medical, cosmetic, industrial and agricultural purposes.

Examples of possible testing systems can be found in the initially mentioned publications and patents, which are included here by way of reference in this regard.

One way to use them is to employ them as pharmaceutical

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preparations (medications) or for the production of medications that in whatever fashion can be employed especially topically but also parenterally. The medications can be formulated in the usual manner with the customary pharmaceutically compatible supports and diluents.

This invention also relates to pharmaceutical preparations that, as active substance, comprise peroxochloric acid, its anions and/or derivatives thereof or salts thereof, and which can be employed especially for the treatment of the initially mentioned diseases. Particularly preferred are preparations for enteral, nasal, buccal, rectal or especially oral administration to warm-blooded subjects, especially human beings, preferably by getting around stomach acid, for instance, with stomach-acid-resistant preparations, such as capsules or Lack tablets [sic] as well as, above all, for local or parenteral as well as intravenous, intramuscular or subcutaneous administration. The preparations contain the active substance by itself or preferably together with one or several pharmaceutically usable support materials. The dosage of the active substance depends on the disease to be treated as well as on the species, the age, weight and the individual condition, the individual pharmacokinetic situation as well as the manner of application. Preferably, the dosage for enteral or especially parenteral application (for example, by way of infusion or injection) (preferably on human beings) is in the range of 0.01 to 100 µMole/kg, especially between 0.1 to 100 µMole, in other words, for example, in a human being with a body weight of 70 kg, that would be 1 mg to 1 g/day, in particular, that would be 8.5 mg up to 850 mg/day in one dose or subdivided over several doses. For

local application, the preferred dose ranges are between 0.1 and 10, in particular, 0.5 and 5 ml/100 $cm^2$ of a 0.1 to 10 millimolar solution (correspondingly more or less for larger or smaller surfaces – applied directly or using soaked gauze).

The invention thus also relates to a method for the prophylactic and/or therapeutic treatment of disease states described herein, preferably for the prophylactic and/or therapeutic treatment of diseases in whose control an increase in tissue regeneration, immune modulation, an improvement of the inoculation reaction or radiation sensitization would be indicated or successful, or two or more of these effects, in particular,

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the treatment of a wound condition in case of a warm-blooded subject comprising the administration of peroxochloric acid, its derivatives and/or anions or of salts thereof in a quantity that is effective against the mentioned diseases for a warm-blooded subject, for example, a human being who requires this kind of treatment.

The invention also relates to a pharmaceutical composition for prophylactic and especially therapeutic treatment of disease conditions described herein, preferably for the prophylactic or therapeutic treatment of diseases in whose control an increase in tissue regeneration, immune modulation, an improvement of the

inoculation reaction or radiation sensitization would be indicated or successful or two or more of these effects, in particular, the treatment of a wound condition in case of a warm-blooded subject who suffers from such a disease containing peroxochloric acid, its derivatives and/or anions or salts thereof in a quantity that is effective in a prophylactic or especially therapeutic manner against the mentioned disease and one or several pharmaceutically usable support materials.

The invention also relates to the method for application or a method for the use of peroxochloric acid, its derivatives and/or anions or salts thereof, for (cosmetic) care of the skin, for example, in case of an inclination toward the development of pimples or the presence of pimples.

Dose unit forms, for example, are coated tablets, tablets, ampules, vials, suppositories or capsules. Other forms of application, in particular, for solutions of peroxochloric acid, its anions and/or derivatives or salts thereof are, for example, ointments, creams, pastes, gels, foams, mouthwashes, drops, sprays and the like. The dose unit forms, for example, ampules, tablets or capsules, preferably contain about 0.05 g to about 1.0 g, especially 8.5 mg to 850 mg of a salt of peroxochloric acid and/or its derivatives with the usual support materials.

The pharmaceutical preparations of the invention at hand are made in the usual manner, for example, by means of

conventional mixing, granulation, coating, solution or lyophilization processes.

In a preferred embodiment, a 0.05 to 1 M solution of a

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peroxochlorate salt and/or a salt of the latter's derivatives can be dissolved in bidistilled water at a pH of equal to or > 10, preferably 10 to 13, in particular, 12.5. This solution is diluted immediately prior to administration with common salt, sodium bicarbonate or potassium bicarbonate and bidistilled water up to isotonia to concentrations of about 1-5 mM and is approached to the physiological pH. This solution is suitable for parenteral, especially intravenous, application.

For a preferred formulation of a medication for topical use, one preferably dissolves peroxochlorate and its derivatives as salts in bidistilled water with concentrations in the lower millimolar or upper micromolar range, preferably in the concentration spread of 0.5-5 mM with a pH of equal to or > 10, in particular, 10 to 13, preferably, for example, 11.5, and are set to isotonia with glycerin, common salt or some other suitable compatible agent that should be as physiological as possible. Other additives are possible. In particular, when the medication is placed in plastic containers, we find those additives suitable that can neutralize the transition metal traces because transition metals are dissolved in the wall

during storage and can catalyze a decomposition of the active substance. Examples of such additives are oligoalcohols or polyalcohols, such as ethylene glycol, desferrioxamine or EDTA (for example, as disodium edeate). The resultant solution can also be directly applied on wounds.

The anion of peroxochloric acid is stable; the acid itself decomposes relatively quickly. A stabilization of the active substance in the medication therefore can be attained via the pH. The active substance solution can be lowered to an approximately physiological value to improve the tolerability immediately prior to use by using a buffer solution. Equation 1 shows that in the blood with a pH of 7.4, there is a chemical half-life of about 2.4 hours. That is sufficient for the development of the pharmacological effect in the entire body because this effect is based not only on the receptor ligand interaction of a conventional pharmacon, but, as noted earlier, it is also tied in with a fast and irreversibly occurring oxidation reaction. The pharmacological effect of that reaction continues so long as the cell and/or its chemically altered structures are preserved, in other words, the reaction is not terminated after the diffusion of an active substance by a receptor.

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Examples of areas where this is indicated and where an increase in tissue regeneration is successful in prophylactic or especially therapeutic terms in treating a disease include tissue regeneration after physical damage (such as, for example, blunt and sharp traumas, shortwave light, radioactive radiation) and after chemical damage (for instance, by tissue toxins such as mustard gas, chemotherapeutics). Another area of employment in this respect is the improvement of wound healing, especially in the case of stubborn, so-called "spontaneous" wounds that refuse to heal due to a basic ailment (for example, Diabetes mellitus, vascular ailments, immune suppression or age-related ailments). Such wounds include especially decubitus or chronic leg ulcers. By wound treatment, we mean here especially the treatment of wounds on the skin, the mucosae and in tissues, such as, for example, liver, heart muscle, or bone marrow.

Another indicated area relates to the prophylactic or especially therapeutic treatment of diseases where immune modulation is successful, especially the improvement of immune defense, in particular, after serious bacterial infections (due both to aerobic and especially also anaerobic viruses) as well as parasitary and viral infections. That applies especially to those infections that cause an energy such as it is known, for example, in the case of microbacterial infections (leprosy and TB). An immune defense weakness, such as it can occur, for

example, in the case of herpes and HIV virus diseases, is a potential area of indication for peroxochlorate treatment. The defense system, which is paralyzed by a pathological tolerance, is again enabled to react physiologically by way of the therapy with the administration of peroxochloric acid that is perceived by the immune cells as artificial danger signals. Such an immunomodulating intervention must by no means be equated with an immune stimulation, which, in the case of AIDS, so far did not prove to be a promising therapy approach. In the early stage after mutagenic gentoxic traumas such as they can be triggered, for example, by gamma radiation or by poisoning with so-called chemical radiomimetics and/or cell traumas that can lead to a malignant cell degeneration with subsequent malignant tumor growth, one can use a co-stimulating immune modulation by means of peroxochlorate.

Another field relates to diseases where, for therapy or

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especially prevention, an improvement of the inoculation reaction is indicated or successful. Here, the invention-based peroxochloric acid, its derivatives, its anions or salts thereof act especially as adjuvant. The improvement of a weak inoculation reaction, such as it is known especially after administration of a so-called peptidovaccine or also the

oxidative mitigation of a live vaccine, are also included in these areas of practical application.

Finally, another indication field is radiation sensitization, for instance, during tumor treatment before or after radiation or simultaneously or in a time overlap.

After a peroxocompound with a therapeutic range of 2 log (i.p. $LD_{50}$ in the case of rats > 0.1 millimole per kg of body weight), peroxochlorate is suitable especially for intratumoral application for radiation sensitization, particularly during relatively short periods of time before or after irradiation, preferably 1 to 24 hours before or after radiation. A tissue tolerable biocidal disinfection is possible in the range of $10^{-5}$–$10^{-4}$ (preferred concentration range at the site).

Peroxochloric acid that represents an analog for the endogenous hydrogen peroxide is present as stable anion with a pH blood value of 7.27-7.53 (mean value 7.4) as a result of the $pK_S$ value of 6.5 ± 0.2, that is to say, to the extent of 89% by mole, and as peroxoacid to the extent of 11% by mole, whereas in the case of hydrogen peroxide ($pK_S$ = 11.9) under physiological conditions, the uncharged metastable $H_2O_2$ share amounts to 99.997% by mole and the hydroperoxide anion (-OOH) amounts to merely 0.003% by mole. It is especially the uncharged acid that therefore can penetrate into the cells, and because (in contrast to $H_2O_2$) it is resistant to catalase, it can also attain higher

concentrations and thus achieve greater effectiveness (for example, in regulation of transcription or translation) than hydrogen peroxide.

In pharmacodynamic terms, however, in both cases, products are, among other things, also effective which originate in vivo because nonionized peroxoacid oxidize the transition metal ion in the hematoporphyrines. Oxidized iron (Fe(III) represents the terminal effective form as Fe(V)=0 or Fe(IV)=0π*. As mild

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oxidants, the Fe(V)=porphyrines in a second step can lead to an oxidative separation of sugar chains, especially membrane-based glycoproteins that perform the regulator functions for cell interactions (Rutishauser, U., Acheson, A., Hall, A. K., Dennis, M. M., Sunshine, J.: "The Neural Adhesion Molecule as a Regulator of Cell-Cell Interactions," Science 240: 53-57, 1988). According to the latest status of immunological information, such glycoproteins that have a regulator function also play a decisive co-stimulating role during the interaction of antigen-presenting cells (APC) with T-lymphocytes (Austyn, J. M. and Wood, K. J.: "4,2-Membrane Molecules in T-Cell Responses in Principles of Cellular and Molecular Immunology," Oxford University Press, 1993).

This means that a hydroperoxide is pharmacologically effective if, on the basis of its stability, it can be

considered as a transport form (prodrug). That applies to peroxochlorate, on the one hand, because it is chemically more stable than the nonionized $H_2O_2$, whereas, on the other hand, in contrast to the latter, it is not attacked by the enzyme catalase that decomposes hydrogen peroxide into water and oxygen gas. This is why hydrogen peroxide in contrast to peroxochlorate cannot be administered intravenously. As substituted hydroperoxide (ROOH; R=H), peroxochlorate offers an additional biochemical advantage when compared to the $H_2O_2$ formed in the body by phagocytes. Substituted hydroperoxide (ROOH; R=H), such as, for example, benzoyl peroxide, peracetic acid, percarboxylic acid, methyl- and ethyl peroxide, form the terminal pharmacological active form of Fe(V)=0 or Fe(IV)=0π* porphoryines. Their speed constants for such an oxidation reaction of hemoproteins in conjunction with a physiological pH are great ($>> 10^6\ M^{-1}\ s^{-1}$). $H_2O_2$ constitutes the terminal pharmacological effective form of Fe(V)=0 or Fe(IV)=0π* porphoryines not only more slowly, but it also destroys them again much faster in a reductive fashion along with the release of molecular oxygen ($O_2$). Substituted hydroperoxides (Jones, P., Mantle, D., Davies, D. M., Kelly, H. C.: "Hydroperoxidase Activities of Ferrihemes. Heme Analogues of Peroxidase Enzyme Intermediates," Biochemistry 16, 18: 3974-3978, 1977) are poor reductors of the terminal pharmacological active form of Fe(V)=0

or Fe(IV)=0π* porphoryines (Frew, J. E. and Jones, P.: "Structure and Functional Properties of Peroxidases and Catalases," et ibid cit. ref. in Advances in Inorganic and Bioorganic Mechanisms, Vol. 8, edited by A. G. Sykes, Academic Press, 1984).

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Pharmacodynamically effective (co)mitogenic oxidants as such usable as medications especially wherever the condition of the immune system has a limiting effect on tissue regeneration regardless of what place on the body it must take place for the purpose of healing and recovering the organism and regardless of the factors by which an immune defense weakness was caused, whether by bacterial, viral or parasitary infections or whether by way of an intensive radioactive radiation exposure, whether by other physical factors, whether by a massive cytotoxic therapy, whether by a metabolism disease such as, for example, Diabetes mellitus or combinations thereof. The peroxochloric acid anions, as (co)mitogenic oxidants, naturally are also effective adjuvants for fighting infections and to correct any infection defense weakness, again regardless of how that weakness was triggered, whether by way of infection, physically, chemotherapeutically or hormonally.

Moreover, the peroxochloric acid anions can, moreover, be used in animal and vegetable tissues that contain endogenous Fe-

porphyrines as disinfectant, especially also in the case of anaerobic infections as well as for careful disinfection of cellular and molecular blood constituents.

The peroxochloric acid anion, for example, can also be used as deodorant in cosmetics (for example, armpits, feet) and in medical care (for example, ulcers) as well as in wastewater disposal when it comes to a high degree of tissue/biotolerability.

The peroxochloric acid anion can be used in the essential and nonessential foods industry as a high-grade, excellent conservation agent. It was found that peroxochloric acid anions, added in traces to high-grade red wines, can immediately after decorking enable those wines to develop their full bouquet while fully preserving the palate and tongue taste.

In technology, especially in chemical technology, the peroxochloric acid anion, for example, can be used for the specifically targeted oxidation of double bonds; for example, to make oxiranes or corresponding diols. It is, for example, possible to oxidize propylene into oxiranes such as propylene oxide or to the corresponding diols. Another industrial purpose

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involves the elimination of odor contamination, such as it is caused especially by composting systems, smoking plants, power plants, etc. One important purpose is the previously mentioned

degermination of, for example, essential foods such as drinking water and use in the agricultural field. Because it is possible to separate CC bonds, one can use peroxochloric acid also for the purpose of reducing the ballast materials out of drinking or bathing water or to detoxify these waters.

The invention-based use is of special importance in the abovementioned elimination of odor contamination deriving, for example, from power plants, because the waste air can also contain heavy metals along with nonmetallic oxides such as sulfur dioxide and nitrous oxides. These heavy metals, of course, as a rule, are trapped by filter systems; nevertheless, the heavy metal mercury does represent a problem because one must guarantee that it is completely present in its bivalent form. That can be done by using the invention-based peroxochloric acid. The invention-based peroxochloric acids involve defined compounds; there are therefore no difficulties when it comes to medication licensing.

Example 1

Production of a Metal Peroxochlorate Solution That Can Contain 50 to 80% by Weight of Metal Chlorite and That Can Be Used, For Example, for Industrial Purposes Such as Body Hygiene, for Piping into Soils and for Wastewaters for Chemical Decontamination.

Chlorodioxide is made in a first reaction vessel by reaction of sodium chlorite and sulfuric acid. The gaseous chlorodioxide is expelled with a nitrogen current and is piped into a second reaction vessel containing half a liter of a molar solution of hydrogen peroxide in water. In a first experiment, no sodium chlorite is added to this solution, whereas in a second experiment one adds 0.1 M sodium chlorite. While the gas is being piped in, the pH value of the reaction solution is monitored by means of a single-stick glass electrode. The pH value is kept at the neutral point by way of automatic addition with a pH stat unit. Caustic soda is used as the base. The progression of the mixing with chlorodioxide is monitored via the quantity of caustic soda that is added. After a consumption

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of 4 mmol of caustic soda lye, the solutions in both experiments contain 1 mmol of the anion of the effective peroxochloric acid anhydride (yield 13% theoretical yield). The content of chlorohydroperoxide is determined by potentiometric titration with hydrochloric acid.

To improve the durability of the reaction product, the pH value is set at more than 10 with caustic soda lye.

Example 2

Production of a Metal Peroxochlorate Solid Substance in a Mixture With About 50% Metal Chlorite (for industrial purposes,

especially to make tablets for the preparation of germ-free drinking water).

The solution containing Na-peroxochlorate (made according to Example 1) is evaporated all the way to beginning crystallization. The crystals are separated from the pure Na-chlorite at about +4°C. These crystals are suctioned off. The mother liquor is subjected to between two and three additional crystallization steps until the precipitating Na-chlorite contains a noticeable amount of Na-peroxochlorate. The content of peroxychlorate [sic] is determined in each case by titration with 0.1 N HCl.

In this way, one can make an approximately 1.5 molar Na-peroxochlorate solution that is then evaporated all the way to dryness. The resultant colorless solid substance contains up to 60% sodium peroxochlorate, sodium chlorite and a small amount of sodium chloride, which are contained in the form of impurities. The Raman spectrum of the solution, thus concentrated, reveals two bands: the band at 799 $cm^{-1}$ is characteristic for chlorite ions, while the band at 1051 $cm^{-1}$ must be matched up with peroxochlorate. The band keeps increasing in intensity starting at 1051 $cm^{-1}$ from step to step during the described enrichment, while the band decreases at 799 $cm^{-1}$. The sodium perchlorate that is that is isomeric with respect to sodium peroxochlorate

in the Raman spectrum shows a band at 938 $cm^{-1}$, whereas the band is 933 $cm^{-1}$ for sodium chlorate.

Example 3

Production of a Peroxochlorate Solution Without Chlorite Impurity (for Pharmaceutical Purposes)

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The peroxochlorate-containing solution is set at a pH value of 5 with an acid (for example, hydrochloric acid, sulfuric acid or the like). A forceful gas current (for example, argon) is used in order immediately to dispel the undissociated acid, and it is then caught in a washing bottle that is filled with a basic solution (preferably an 0.1 M NaOH). After just a few minutes, the peroxochloric acid is completely expelled from the starting solution and is trapped as a stable anion about 70% undecomposed. The trapped solution only contains stable metal peroxochlorate and, after retitration to the physiological pH with acid (for example, HCl or $CO_2$), a little bit of salt (for example, NaCl or $NaHCO_3/Na_2CO_3$) along with traces of NaOH.

Example 4

Production of a Peroxochlorate Solution with Chlorite Impurities

A solution as concentrated as possible of a metal, ammonium or alkyl ammonium peroxochlorate that can have impurities of chloride ions is dripped in to a buffer solution preferably with a pH of between 3.5 and 5.5 (for instance, citric acid or

phosphor acid buffer). The pH value is monitored with a glass electrode. It must not be higher than 6. Using a forceful gas current (for example, nitrogen, oxygen, argon or also $CO_2$-free air), the peroxochloric acid is expelled and is piped into a battery of three serially connected washing bottles, which are filled with a base. One can use any desired bases. Suitable, for example, would be caustic soda lye or potash lye but also ammonia solution and solutions of alkaline earth or zinc hydroxide as well as solutions containing nitrogen bases. One can also employ mixtures of solvents as well as water-containing or anhydrous organic solvents. One must check to make sure that the pH value in the water bottles will, if at all possible, not drop below a value of pH 10.

Example 5

Production of Pure Crystalline Metal, Ammonium or Alkyl Ammonium Peroxochlorate

The chlorite-free solution of metal, ammonium or alkyl

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ammonium peroxochlorate solution made in Example 3 or 4 is concentrated up to beginning crystallization by gassing with argon. In the case of sodium as a metal ion, colorless crystals in the form of little rods will be separated on the sodium peroxochlorate. The crystals are suctioned off, they are washed with a little water and they are dried in air.

When 5 mg of the sodium salts are dissolved in 0.5 ml of water, then one can recognize the characteristic band as a sharp peak at 1051 $cm^{-1}$ in the Raman spectrum. Titration with 0.1 M of hydrochloric acid results in a consumption of 0.4 ml.

Example 6

To a solution of 100 g of sodium chlorite in 200 ml of water, one cautiously adds, drop by drop while stirring, hydrochloric acid (96%). Using a strong gas current ($N_2$ or $O_2$), the generated chlorodioxide is expelled. The $ClO_2$-containing gas current is piped via three serially connected washing bottles, each of which is filled with 30 ml of a 2 M $NaClO_2$ solution with a pH of 11 into a solution of 15 ml of 30% hydrogen peroxide in 35 ml of water, which beforehand has been raised to a pH of 12 by adding 4 M caustic soda lye. While the gas is being piped in, the pH value is checked with a glass selector. The pH value is kept at 12 by adding $H_2O_2$. The prepared $H_2O_2$ is consumed when the gas piping results in a yellow coloration. The solution is then again discolored with one drop of $H_2O_2$. The peroxochlorate-containing solution is dripped, while stirring, into a solution of 500 g of citric acid in 3 liters of water, which solution beforehand has been set at a pH of 4.5 with 2 M of caustic soda lye. During the addition, the peroxochloric acid is expelled with a strong gas current ($N_2$ or $O_2$) and is trapped in there serially connected washing bottles that have been filled with 50

ml each of 0.1 M of NaOH. After the pH value in the water bottles has dropped to 10, the contents of the water bottles are combined and are concentrated to dryness. Yield: 1.5 g of dry sodium peroxochlorate.

Example 7

Exemplary Embodiment

In 10 patient case examples with chronic, infected wounds that had resisted therapy for 4 months up to one year (2 diabetic foot wounds, 4 Ulcera venosa, 1 Ulcus after laser treatment of a finger wart, 1 finger wound connected with scleroderma (healing after treatment on the left; on the right,

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dried but not healed), 2 wounds with leukocytoclastic vasculitis), one can achieve healing with external wound moist treatment with 0.01 to 0.001% peroxochlorate in physiological common salt solution. In these cases when sodium peroxochlorate is used in this fashion, "under compassionate use," complete wound closure lasts no longer than two months.

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CLAIMS

1. Peroxochloric acid, its derivatives and/or anions or salts thereof.

2. Peroxochloric acid, its derivatives and/or anions or salts thereof according to Claim 1 in a water-containing or aqueous solution.

3. Salts of peroxochloric acid or its derivatives according to Claim 1.

4. Alkali metal, alkaline earth metal, zinc, ammonia and amino salts of peroxochloric acid or its derivatives.

5. Process for the production and isolation of peroxochloric acid, its derivatives and/or anions or salts thereof according to one of Claims 1 to 3, characterized in that chlorodioxide is mixed with an aqueous or water-containing solution of hydrogen peroxide at a pH value of ≥ 6.5, that one lowers the pH value by adding an acid and that one expels the gaseous free peroxochloric acid or its derivatives with an inert gas and traps it.

6. Process according to Claim 5, characterized in that one traps the free acid or its derivatives in a cooling trap.

7. Process according to Claim 5, characterized in that one pipes the free acid or its derivatives into an aqueous alkaline solution.

8. Process according to Claim 7, characterized in that as base, one uses an alkali metal, alkaline earth metal, zinc or nitrogen base or a hydroxide of a quaternary ammonium salt.

9. Process according to Claim 8, characterized in that one isolates the resultant salts by concentration or fractionated crystallization.

10. Process according to Claim 7 or 6, characterized in that

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one stabilizes the resultant solutions by raising the pH value.

11. Pharmaceutical preparation containing peroxochloric acid, its derivatives or anions or salts thereof according to one of Claims 1 to 4.

12. Pharmaceutical preparation according to Claim 11, characterized in that it is formulated for parenteral or topical administration.

13. Use of peroxochloric acid, of its derivatives and/or anions or salts thereof according to one of Claims 1 to 4 as oxidant, disinfection, conservation agent and/or bleaching agent.

14. Use of peroxochloric acid, of its derivatives and/or anions or salts thereof according to one of Claims 1 to 4 for the treatment of the human or animal body, preferably for prophylactic and/or therapeutic treatment - especially for a warm-blooded subject, in particular, a human being - of diseases in whose control an increase in tissue regeneration, an immune modulation, an improvement of the

vaccination reaction and/or radiation sensitization is indicated or successful, especially for wound treatment.

15. Use of peroxochloric acid, of its derivatives and/or anions or salts thereof according to one of Claims 1 to 4 for making a pharmaceutical preparation for the treatment of the human or animal body, preferably for prophylactic and/or therapeutic treatment – especially for a warm-blooded subject, in particular, a human being – of diseases in whose control an increase in tissue regeneration, an immune modulation, an improvement of the vaccination reaction and/or radiation sensitization is indicated or successful, especially for wound treatment.

16. Peroxochloric acid, its derivatives and/or anions or salts thereof according to one of Claims 1 to 4 for use in a process for the treatment of the human or animal body.

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17. Method for the treatment of disease states, preferably for prophylactic and/or therapeutic treatment – in particular, for a warm-blooded subject, especially a human being – of diseases in whose control an increase in tissue regeneration, an immune modulation, an improvement of the vaccination reaction and/or radiation sensitization is indicated or successful, in particular, regarding a wound disease in a warm-blooded subject comprising the

administration of peroxochloric acid, its derivatives and/or anions or salts thereof according to Claim 1 in a quantity that is effective against the mentioned diseases for a warm-blooded subject, for example, a human being who requires this kind of treatment.

18. Pharmaceutical composition for prophylactic and especially therapeutic treatment of diseases - preferably for prophylactic and/or therapeutic treatment, especially in a warm-blooded subject, in particular, a human being - of diseases in whose control an increase in tissue regeneration, an immune modulation, an improvement of the vaccination reaction or radiation sensitization is indicated or successful, in particular, a wound disease in a warm-blooded subject who suffers from such a disease containing peroxochloric acid, its derivatives and/or anions or salts thereof according to Claim 1 in a quantity that is effective prophylactically or especially therapeutically against the mentioned disease and one or several pharmaceutically usable support materials.

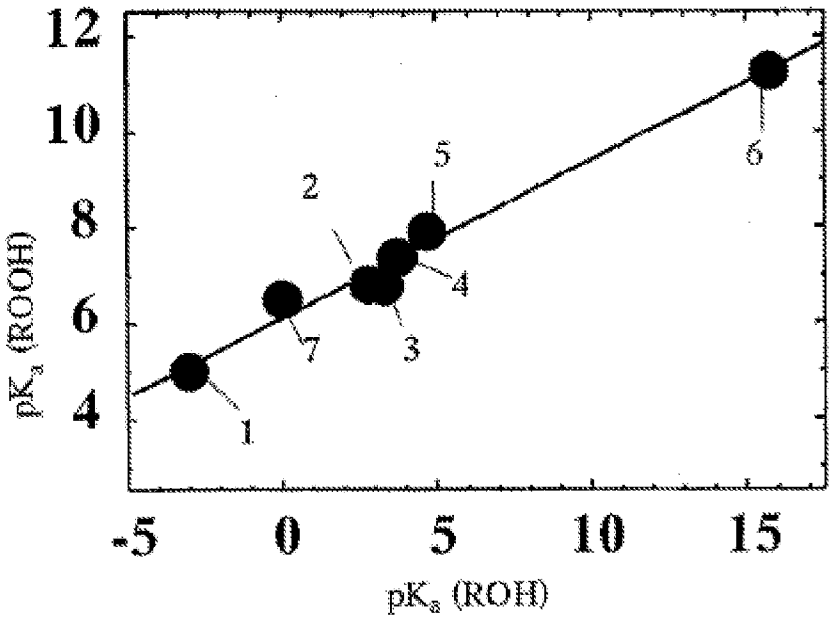


Fig. 1